

PSJ3

Exhibit 490

From: Johnson, Anne
Sent: Monday, June 30, 2014 3:11 PM
To: Ducca, Anita
Subject: FW: For EC call

Here you go. The last call was on Friday, April 18. And then, of course, the EC & Bd Mtgs were on June 1 where many updates were given.

From: Kelly, Patrick
Sent: Thursday, April 17, 2014 12:16 PM
To: Johnson, Anne; Gray, John
Subject: For EC call

Federal Legislative update:

E&C Health Subcommittee Hearing:

HDMA testified before the Energy and Commerce Health Subcommittee on April 7 in support of the Marino/Blackburn legislation H.R. 4069. The hearing also included testimony from Dr. Janet Woodcock from FDA and Joe Rannazzisi from DEA. The legislation appears to have bipartisan support from members of the subcommittee.

Attorney General Holder:

On Tuesday April 8, the House Judiciary Committee held a hearing "Oversight of the U.S. Department of Justice" and Attorney General Eric Holder was the only witness. During the hearing, Rep. Marino (R-Pa.) asked AG Holder about how DOJ can work more collaboratively with supply chain stakeholders. Marino mentioned the intent of his bill (H.R. 4069) is to facilitate collaboration.

Attorney General Holder responded very positively and said that patient access to medications should be a top priority. He also mentioned that DOJ should not lose sight that there are companies trying to do the right thing and implied that they should have the guidance they need. He also offered to meet with companies to explore ways they can work together and suggested that Rep. Marino help facilitate that conversation.

Representative Marino is sending a follow-up letter to the Attorney General offering to bring members of the supply chain together for a meeting with the AG. HDMA members will be encouraged to participate in this meeting when and if it is scheduled.

LIFO Update:

HDMA continues to work with the LIFO Coalition under the leadership of the National Association of Wholesalers (NAW). Earlier this year House Ways and Means Committee Chairman Dave Camp (R-MI) introduced a comprehensive Tax Reform proposal that included repeal of the LIFO accounting standard. For a variety of reasons, this legislation is unlikely to move this year. However, HDMA and the numerous members of the LIFO Coalition are working to educate their Congressional representatives about the significant impact LIFO repeal could have on large volume businesses.

In the States:

Maryland Distributor Notification Bill Dies in Senate:

Legislation that would have required pharmaceutical distributors to give pharmacies a 30-day notice prior to limiting access to any drugs or devices was unanimously defeated in the Senate Education, Healthcare and Environmental Matters Committee. HDMA was able to retain the top lobbying firm in the state (with less than 30 days remaining in the legislative session) on the eve of this bill passing out of the House of Representatives. This was not a budgeted expenditure.

Ohio Commercial Activity Tax (CAT-Tax):

HDMA re-engaged our contract lobbyist in Columbus (originally cut due to budget constraints) to oppose an increase in the state's Commercial Activities Tax. Ohio Governor John Kasich (R) is attempting to reduce the state's personal income tax and has proposed a series of program cuts and revenue generators to help underwrite the cost of the measure. There are numerous provisions that must be implemented to secure this measure. We do not expect any immediate activity on the measure to increase the CAT.

NABP Prescription Drug Abuse Stakeholders Group:

NABP has invited HDMA to participate in a stakeholders group to discuss curbing prescription drug abuse. The stakeholders group was originally convened by NABP in an effort to improve dialogue between physician groups and pharmacy groups on prescribing and dispensing practices to prevent drug abuse and diversion.

The group met April 16 in Chicago to discuss "Challenges" and "Suggestions" for prescribing and dispensing controlled substances. The group eventually hopes to develop two documents: 1.) a "Red Flags" document outlining situations where processes should be implemented to ensure the legitimacy of a prescription for a controlled substance. 2.) A document providing guidelines on how to engage in, and improve the dialogue between stakeholders to address Red Flags. It is clear that the group is still in the process of consensus development – with another meeting of the group scheduled for the June/July time frame.

HDMA joins the following groups as members of stakeholders group"

American Academy of Family Physicians
American Medical Association
American Pharmacists Association
American Society of Anesthesiologists
American Society of Health-System Pharmacists
American Osteopathic Association
Cardinal Health
CVS Caremark
DEA
Express Scripts
HDMA
NACDS
NCPA
Pharmaceutical Care Management Association
PhRMA
Purdue Pharma
Rite Aid
Walgreens

Regulatory Updates

The Traceability Implementation Work Group (TIWG – "Tee Whig")

The TIWG is in the process of finalizing a letter to FDA regarding methods for transmitting transaction information for compliance with the Drug Supply Chain Security Act (DSCSA). Final comments are due to FDA by Monday 4/21.

FDA will be holding a public workshop on May 8-9 on the same topic regarding transmitting the data. HDMA will be participating.

Hydrocodone Rescheduling: (***Will have an update on this situation later today after the RAC Call at 3:00***)

HDMA is in the process of finalizing comments on DEA's proposed rule to place hydrocodone-combination products (HCPs) currently in Schedule III, into Schedule II. The biggest impact is the requirement for Schedule II products to be

stored in vaults. Many of our members would have to expand their vaults considerably to accommodate all the HCPs involved.

IMPORTANT: We don't yet have consensus on HDMA's comment position.

- McKesson wants us to request an exemption from the vault requirement so that HCPs can stay in cages. They could agree to "grandfathering" the old vaults as a "back-up" position. (There is plenty of justification for an exemption i.e., there's no data showing HCPs are stolen from current cage storage, DEA has a provision in the regulations where they can make a finding that storage is in "substantial compliance", and there are solid reasons why security is much tighter since the vault regulations came out in 1972.)
- Cardinal wants us to only request enough time to construct the vaults. They say they're concerned about possible negative DEA reaction to asking for more.
- All others are ok with a compromise: *i.e.*, grandfathering, with asking for more time as a back-up.